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CENTRAL FAX CENTER****AUG 15 2006****Serial No. 10/088,732
Art Unit: 1617****REMARKS**

Applicants respectfully request that the finality of the rejection be reconsidered and withdrawn. In the final rejection, the Examiner has presented completely new grounds of rejection in every respect which grounds of rejection were not necessitated by Applicants' minor amendment to the claims. Applicants invite the Examiner's attention to MPEP Section 706.07(a). Applicants submit that under the guidelines of Section 706.07(a) the finality of the rejection is improper and must be withdrawn.

Before discussing the rejections over the prior art, Applicants deem it prudent to set forth what they consider to be their invention. As presently claimed, the invention is directed to a composition comprising:

(a) an oligoglycoside selected from the group consisting of alkyl oligoglycosides, alkenyl oligoglycosides and mixtures thereof;

(b) a foam stabilizer selected from the group consisting of partial esters of tartaric acid with C₆₋₂₂ fatty alcohols, salts of partial esters of tartaric acid with C₆₋₂₂ fatty alcohols, partial esters of malic acid with C₆₋₂₂ fatty alcohols, salts of partial esters of malic acid with C₆₋₂₂ fatty alcohols, partial esters of citric acid with C₆₋₂₂ fatty alcohols, salts of partial esters of citric acid with C₆₋₂₂ fatty alcohols, and mixtures thereof; and

(c) optionally, at least one active ingredient selected from the group consisting of cosmetic active ingredients, pharmaceutical active ingredients, and mixtures thereof, with the proviso that (a) and (b) are employed in a ratio by weight of from about 60:40 to 40:60.

As presently claimed In the composition of claim 13, the critical portions of the

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composition are a mixture of an alkyl oligoglycoside or alkenyl oligoglycoside with a foam stabilizer comprising the partial esters of tartaric acid, maleic acid and citric acid with C₆₋₂₂ fatty alcohols and salts thereof.

The composition unexpectedly has improved dermatological and ophthalmic mucus membrane compatibility and excellent foam stability. Applicants respectfully submit that the present invention is not obvious over the prior art references cited by the Examiner.

Claims 13-16, 19-22 and 25-27 stand rejected under 35 USC 103(a) as unpatentable over Kahre et al. (US 6,432,419) in view of Ira Weil (US 5,089,531 hereinafter Weil). Applicants respectfully submit that Kahre et al. and Weil whether considered alone or in combination neither teach nor suggest the present invention.

Kahre et al. disclose and claim a cosmetic or pharmaceutical composition containing an auxiliary or an additive and

1) a nonionic surfactant selected from the group consisting of alkyl or alkenyl oligoglycosides and fatty acid-n-alkyl polyhydroxyalkylamides; and

2) a fatty compound wherein said fatty compound consists of an oil selected from a group consisting of

(a) polyol polyhydroxystearates; and

(b) hydroxycarboxylic acid esters wherein the fatty compound and the nonionic surfactants are present in a ratio by weight of 10:90 to 90:10 and wherein the total quantity of auxiliaries and additives in a composition is from about 1 to 50% by weight based on the weight of the composition.

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It is the Examiner's contention that the term "hydroxycarboxylic acid esters" refers to both full esters and partial esters of hydroxypolycarboxylic acids. Applicants respectfully submit that the Examiner's interpretation of the claim (ester) is untenable in view of teachings of the reference. The hydroxycarboxylic acids useful in the practice of the Kahre et al. invention must be an oil (see abstract; claim 1; col. 1, line 34). Applicants respectfully submit that as far as Applicants are aware, the partial esters of the hydroxypolycarboxylic acids useful in the practice of the present invention are not oils as required in the Kahre et al. disclosure.

Applicants invite the Examiner's attention to Weil at col. 11, lines 8-10, 40-43 and 47-50. At these points, Weil teaches that the partial esters are solid materials and not the oil which is required in the practice of the Kahre et al. invention. Further, at col. 13, lines 40-43 and 55-58; Weil teaches that the monododecyl alcohol partial esters and the monotetradecyl esters and pentadecyl esters of citric acid are solids and recovered as a precipitate.

In addition, Applicants invite the Examiner's attention to US 2,518,678 cited at col. 2, line 5 of Weil. Particularly, Applicants invite the Examiner's attention to col. 3, lines 64, 65; col. 5, lines 2-4; and 54-57. In addition, Applicants invite the Examiner's attention to the '678 patent at col. 7, lines 1 and 2. The patent clearly shows that the partial esters of citric acid with alcohols in the range presently claimed are solid materials. The materials set forth are recovered by precipitation and the melting points of the mixtures of the various esters is set forth. Applicants submit that if the partial esters were purified, their melting

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points would be even higher.

Applicants further invite the Examiner's attention to US 2,523,792 (hereinafter Vahlteich et al.) which discloses that mixtures of mono, di and triesters of citric acid are relatively high melting solids (col. 2, lines 8-13, col. 4, lines 73-75 and col. 7, lines 50, col. 8, line 5) which clearly shows that monostearyl citrate has a melting point of 51-68°C and that trioleyl citrate forms an oil-like material in which the monostearyl citrate is soluble.

US 4,271,032 cited at Weil, col. 3, line 5, discloses that the dodecylmonoester of citric acid was an amber oil which solidified to a cream colored soft solid (col. 4, lines 55-60).

Applicants respectfully submit that from the available literature, it would appear that the partial esters of hydroxypolycarboxylic acids according to the present invention are not oils but solids and would not be interchangeable with the oils required in the Kahre et al. composition.

In addition, one of the unexpected attributes of the partial esters of the hydroxypolycarboxylic acids is the ability as a foam stabilizer for the alkyl and alkenyl oligoglycosides. This ability is not disclosed in the Kahre et al. application since at col. 6, lines 45, 46, Kahre et al. teaches that the fatty acid alkanolamides which are useful in the invention also serve as foam stabilizers. Applicants submit that a foam stabilizer is not required in the composition of the present invention since the partial esters of the hydroxypolycarboxylic acids provide this function to the composition.

In the previous response which is incorporated herein by reference in its entirety,

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Applicants pointed out that three of the four preferred hydroxycarboxylic acids useful in the Kahre et al. composition are monoacids and therefore can only form a full ester. In addition, Kahre et al. is completely silent concerning the mucus membrane compatibility and low irritation effect of the composition of the present invention. Applicants respectfully submit that the foam stabilization and the improved irritability index of mucus membrane compatibility are neither taught nor suggested by Kahre et al. Applicants submit that the composition of the present invention is different and neither taught nor suggested by Kahre et al. and show the unexpected foam stabilization and mucus membrane compatibility which is unexpected in view of Kahre et al.

As set forth above, Kahre et al. is deficient in neither teaching nor suggesting use of a partial ester of a hydroxypolycarboxylic acid and in particular use of such compounds which are solids. Kahre et al. clearly requires that the esters of the hydroxycarboxylic acids are oils which Applicants submit are not solid at room temperature. In addition, Kahre et al. provides four examples of preferred hydroxycarboxylic acids, three of which are monocarboxylic acids which can only be used to form a full esters. The examples in Kahre et al. utilize a full ester. There is not one mention of the use of a partial ester of a hydroxypolycarboxylic acid in the entire Kahre et al. disclosure.

The deficiencies in Kahre et al. are not cured by combination with Weil. Weil is directed to a skin treatment composition comprising a physiologically acceptable carrier and 1-35% by weight of a salt of a monoester of citric acid. The monoester of citric acid is an ester of citric acid with 10-18 carbon atom alcohol. At col. 3, lines 24-31, Weil teaches:

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"Some conventional methods of synthesizing monoesters of citric acid yield a mix of mono-, di-, and triesters of citric acid. The mixed mono-, di- and triester products of these methods is impractical in many applications. Only the monoester is soluble in alkaline aqueous systems. Additionally, the di- and tri-esters severely limit foaming."

Applicants respectfully submit that in view of the teachings of Weil, one skilled in the art would not expect that the addition of the partial esters of the hydroxypolycarboxylic acids would be useful as a foam stabilizer. In particular, in combination with an alkyl or alkenyl oligoglycoside since Kahre et al. teach that the compositions containing the full ester of the hydroxypolycarboxylic acids require alkanolamides as foam stabilizers. Weil teaches that the monoesters of citric acid may be neutralized with various alkaline materials which become the cation of the monoester salt. The solid precipitate which forms as a solid of a monoester of citric acid of the formulas (I) or (II) above (col. 11, lines 8-11).

Weil further teaches at col. 11, lines 40-50, that the isomers may be isolated from one another by known methods, among which are re-crystallization techniques and at lines 47-50 teaches:

"Adding an additional 1.5 parts ethyl ether induces precipitation. Once precipitation is complete, the solution may be filtered yielding pure symmetrical ester with melting point of 78°-80.5°C."

Applicants submit that Weil clearly teaches that the monoester of citric acid with alcohols form a solid which melts at a temperature of 78°-80.5°C. Again, Applicants submit that the compounds disclosed in Weil are not useful in the Kahre et al. invention which requires that the ester be an oil. In addition, at col. 13, lines 40-58, Weil teaches that the

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lauryl alcohol monoester of citric acid and C₁₄-C₁₅ monoesters of aliphatic primary alcohol form a mixture of disodium salts of monotetradecyl ester and monopentadecyl ester of citric acid and are recovered as a precipitate. Applicants submit that this section of Weil clearly teaches that the partial esters are solids and would not be useful as the oil component of the Kahre et al. composition. Applicants respectfully submit that the prior art clearly teaches that the partial esters of the hydroxypolycarboxylic acids are solid material which do not conform to the use of esters which are an oil in the composition of Kahre et al. Applicants therefore respectfully submit that the combination of Kahre et al. with Weil neither teaches nor suggests the present invention.

The Examiner's rejection is based on speculation and supposition which bears no relation to the reality of the teachings of Kahre et al. and Weil.

It is clear that Kahre et al. requires that the esters of the hydroxycarboxylic acids (which are mostly monocarboxylic acids) be an oil. In addition, Kahre et al. teaches that foam stabilizers such as the alkanolamides are useful in the composition. Applicants submit that one skilled in the art would not be taught that the esters useful in the composition of Kahre et al. would provide foam stabilization properties to the composition. In addition, since the prior art teaches that the partial esters of the hydroxypolycarboxylic acids are generally solid materials, one skilled in the art would not be lead to attempt to substitute the partial esters of the hydroxypolycarboxylic acids for the oils required in the Kahre et al. composition. Applicants submit that Kahre et al. would teach one skilled in the art away from utilizing partial esters of hydroxycarboxylic acids, which are solids, in the

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composition. The use of solid partial esters in the Kahre et al. composition would be contrary to the teachings of the reference. Applicants request that the rejection be reconsidered and withdrawn.

The Examiner states:

"Weil teaches composition incorporating a salt of a monoester of citric acid (a partial ester) that can be used in skin treatment compositions, and that impart a pleasant smoothness to the skin (see abstract, in particular.) Weil teaches that the hydrophobic group having the ester linkage to the citric acid desirably has 10 to 18 carbon atoms (see abstract, in particular), and thus teaches providing a partial ester of citric acid with a fatty alcohol group having a number of carbon atoms that falls within the limitations of the fatty alcohols recited in claims 13-16, 19-22 and 25-27. Regarding claims 16 and 22, Weil teaches that salts of the monoester that are suitable for such skin treatment compositions include alkaline earth metals and ammonium, among others (see column 10, line 60 through column 11, line 10, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the esters of citric acid and fatty alcohols as in Kahre et al, in the form of the specific partial esters or partial ester salts as taught by Weil, because Kahre et al. teaches the composition having fatty compounds comprising esters of citric acid with fatty alcohols that are suitable for use in cosmetic composition, and Weil teaches that partial esters of citric acid with fatty alcohols and their salts are suitable for cosmetic compositions such as skin treatment. Accordingly, one of ordinary skill in the art would have been motivated to provide the esters of Kahre et al. in form of partial esters as taught by Weil, with the expectation of providing a composition having fatty compounds that are suitable for cosmetic use."

Applicants respectfully request that the Examiner reconsider her understanding of the teachings of Weil. Weil discloses a skin treatment composition comprising a physiologically acceptable carrier and 1-35% by weight of a salt of a monoester of citric acid. The skin treatment composition imparts a pleasant smoothness to the skin and may be incorporated in several products to treat skin dryness. However, Weil is completely

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silent concerning a composition containing an alkyl or alkenyl oligoglycoside. Weil is limited to the monoesters and fails to recognize the utility of the diesters. In addition, Weil teaches that the di- and triesters severely limit foaming (col. 3, lines 28-31). As shown in the Examples of the present application, the compositions 1, 2 and 3 provide similar amounts of foam and the partial ester salts provide similar relative amounts of foam stability and mucus membrane compatibility. This is unexpected in view of the teachings of Weil and Kahre et al.

In addition, as pointed out supra, the salt of the monoester of citric acid disclosed in Weil is a solid material (col. 11, lines 8-10). The isomers are isolated by one of the known methods among which are re-crystallization techniques (see col. 11, lines 40-50). Applicants respectfully submit that one skilled in the art would not expect to form a useful composition by substituting the solid partial esters of Weil for the oil required in the Kahre et al. composition. One skilled in the formulation art would realize that there is no guarantee of success when one substitutes a solid composition for a oil in a cosmetic preparation. Applicants therefore respectfully submit that Weil does not cure the deficiencies in Kahre et al. and the combination of references neither teaches nor suggests the present invention.

Since the compositions are different, one skilled in the art would expect that the different compositions would have different properties and therefore, claims 19-22 and 25-27 are not obvious over the combination of Kahre et al. with Weil.

Claims 13-15, 16-21 and 23-27 stand rejected under 35 USC 103(a) as

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unpatentable over Kahre et al. in view of Wachter et al. (US 5,770,185). Applicants respectfully submit that Kahre et al. and Wachter et al, whether considered alone or in combination neither teach nor suggest the present invention. Kahre et al. has been discussed in great detail in the previous response which is incorporated herein by reference and supra. However, Kahre et al, is deficient as a reference since it is limited to esters of hydroxycarboxylic acids which are oils and does not teach or suggest use of partial esters which as discussed above are known to be solids. The deficiencies in Kahre et al. are not cured by combination with Wachter et al. Wachter et al. is directed to a process of suppressing body odor by applying to the skin a topical composition containing a fat-soluble hydroxycarboxylic esters formed by reacting hydroxycarboxylic acids with various carboxylic acids or alcohols. The hydroxy carboxylic acids can even be reacted with alkyl glycosides (component (d)).

Wachter et al. falls as a reference since it neither teaches nor suggests that the esters of the hydroxycarboxylic acid be mixed with an alkyl or alkenyl oligoglycoside to form a composition with improved mucus membrane compatibility and whose foam is stabilized by the partial esters. The esters useful in the practice of the Wachter et al. invention are fat-soluble partial esters. The effective esters disclosed in Wachter et al. are not considered to be esters of fatty alcohols with hydroxypolycarboxylic acids and comprise ester of materials such as esters of citric acid and hydrogenated tallow fatty acid monoglycerides, esters of diacetyl tartaric acid and hydrogenated tallow fatty acid monoglycerides, and citric acid tocopherol esters. In addition, esters of the

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hydroxypolycarboxylic acids with fatty alcohols containing 12 to 30 carbon atoms can be utilized. However, Applicants respectfully submit that as discussed above and as shown in the prior art, the partial esters of hydroxypolycarboxylic acids are not oils but are solid materials. Applicants therefore respectfully submit that there would be neither teaching nor suggestion to include the solid partial esters of the hydroxypolycarboxylic acids in the composition of Kahre et al. with any expectation that the composition would be useful, provide foam stabilization and improve the mucus membrane compatibility of the mixture of the alkyl or alkenyl polyglycoside with the partial ester.

The Examiner's rejection appears to be based on her assumption that all of the esters of hydroxypolycarboxylic acids are the same whether they be partial esters or full esters. Applicants submit that since Kahre et al. requires that the esters be oils, and the partial esters useful in the practice of the present invention are solids, Applicants respectfully submit that the compositions are not the same and one skilled in the art would not be lead to the composition of the present invention with its unexpected properties of improved foam stability and improved mucus membrane compatibility. Applicants respectfully submit that the rejection under 35 USC 103(a) over the combination of Kahre et al. with Wachter et al. is untenable and respectfully request that the rejection be reconsider and withdrawn.

Applicants submit that there is no mention in any of the references, relied on by the Examiner, that the addition of the hydroxypolycarboxylic acid partial esters to an alkyl or alkenyl oligopolyglycoside, Improves the foam stability and the mucus membrane

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compatibility of the polyglycoside. Kahre et al. teaches that the composition contains esters of the hydroxypolycarboxylic acids and exemplifies only full esters. Applicants respectfully submit that there is no teaching or suggestion in the prior art cited by the Examiner for one skilled in the art to attempt to improve the foam stability or mucus membrane compatibility by mixing the alkyl or alkenyl oligoglycoside with the partial esters of hydroxypolycarboxylic acids. As discussed supra, Kahre et al. at column 6, lines 44-46 teach that fatty acid alkanolamides serve as foam stabilizers in compositions of the invention containing an alkyl or alkenyl oligoglycoside and the hydroxycarboxylic acid esters.

If the Examiner states that the properties would be inherent in the mixture, Applicants respectfully submit that they have found a small area within the broad teachings of Kahre et al. in which the composition has unexpected properties such as improved foam stability and improved mucus membrane compatibility. Kahre et al. clearly teaches that alkanolamides serve as foam stabilizers in the composition of the invention. Applicants submit that this teaching would teach one skilled in the art away from expecting that the partial esters of hydroxypolycarboxylic acids would improve the foam stability of the composition. Applicants therefore respectfully submit that the Examiner's rejection is based on speculation, supposition and hindsight reconstruction of Applicants' invention which is not a proper grounds for a rejection under 35 USC 103(a).

Applicants have clearly shown that the partial esters of the hydroxypolycarboxylic acid useful in the practice of the present invention are solid materials and not the oils

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required in the Kahre et al. composition. Applicants therefore respectfully submit that one skilled in the art would have to make an entirely new invention by incorporating the solid partial esters of hydroxypolycarboxylic acids of the present invention into the Kahre et al. composition. Applicants therefore respectfully submit that Kahre et al., Weil and Wachter et al., whether considered alone or in combination neither teach nor suggest the present invention.

The Examiner has maintained the rejection over double patenting obviousness-type over claims 1-10 of Kahre et al. in view of Weil or in the alternative over claims 1-10 of Kahre et al. in view of Wachter et al. Applicants respectfully submit that the claims are not identical and are not obvious over each other.

As pointed out above, Kahre et al. requires that the ester of the hydroxypolycarboxylic acid (which as shown are full esters) are oils which are required in the Kahre et al. composition. Applicants have clearly shown that the partial esters of hydroxypolycarboxylic acids useful in the practice of the present invention are solid materials. The use of the solid hydroxypolycarboxylic acid esters useful in the practice of the present invention is not obvious over the teachings of the combination of references and therefore the double patenting rejection must be reconsidered and withdrawn.

At pages 13 and 14 of the Official Action, the Examiner appears to try to justify the position that an oil is the same as a solid. This would be equivalent to stating that corn oil is the same as butter or lard since they are comprised of triglycerides of fatty acids; or that mono and diglycerides have the same properties as triglycerides. Applicants submit that

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this position is not tenable in view of the known differences in use function and properties of the liquid triglycerides in relation to the solid triglycerides and mono and diglycerides in relation to triglycerides. Clearly, the different materials have different properties and these properties are useful for different purposes. Applicants submit that there is no assurance in the combination of reference that the substitution of a solid hydroxypolycarboxylic partial ester would have the same function as a liquid hydroxycarboxylic acid ester in the Kahre et al. composition. Clearly, there is neither teaching nor suggestion to substitute for the liquid or oil hydroxycarboxylic acid useful in Kahre et al., the solid partial ester compositions disclosed in Weill and Wachter et al. In addition, the unexpected properties (foam stabilization and improved mucus membrane compatibility) which arise from utilizing the solid hydroxypolycarboxylic acid partial esters in place of the oil required Kahre et al. is neither taught nor suggested by the combination of references.

In view of the above discussion, Applicants respectfully submit that the application is in condition for allowance and favorable consideration is requested.

Applicants further submit that the final rejection is improper and respectfully request that the finality of the rejection be withdrawn and prosecution continued:

The Examiner has maintained that claims 15 and 21 are product-by-process claims. Applicants respectfully request that the Examiner reconsider her understanding of product-by-process claims.

The term "derived from the same type of fatty alcohol" is not a process limitation in the claims but is a structural limitation which indicates that both (a) and (b) contain residues

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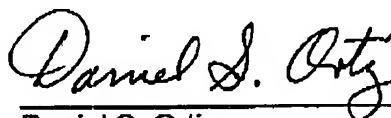
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of the same type of fatty alcohol. Applicants further submit that all claims which contain what may appear to be process limitations are not product-by-process claims. Applicants invite the Examiner's attention to *In re Gamero*, 412 F.2d 276, 162 USPQ 221, 223 (C.C.P.A. 1969) and *Hazani v. United States Int'l Trade Comm'n*, 126 F.3d 1473, 44 USPQ 2d 1358, 1363 (Fed. Cir. 1997).

As used in the present application, the phrase objected to by the Examiner clearly is a structural limitation and does not convert the product claim into a product-by-process claim. Applicants submit that all compounds are derived from other materials and term "derived" is not a process limitation in the product claim. Applicants therefore respectfully request that the Examiner reconsider and withdraw the rejection.

In view of the above discussion, Applicants request favorable consideration of the claims and withdrawal of the final rejection.

Respectfully submitted,



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